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UNITED STATES PATENT APPLICATION

FOR

SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT

BY

JOSEPH C. CAUTHEN

DESCRIPTION

SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT

Cross-Reference to a Related Application

[001] This application is a continuation of U. S. Serial No. 09/484,706, filed January 18, 2000 which claims the benefit of U.S. Provisional Application No. 60/160,710, filed October 20, 1999.

Field of the Invention

[002] The invention generally relates to a surgical method of intervertebral disc wall reconstruction with a related annulus stent augmenting the repair. The effects of said reconstruction are restoration of disc wall integrity and reduction of the failure rate (3-21%) of a common surgical procedure (disc fragment removal or discectomy). This surgical procedure is performed about 390,000 times annually in the United States.

Background of the Invention

[003] The spinal column is formed from a number of vertebrae, which in their normal state are separated from each other by cartilaginous intervertebral discs. The intervertebral disc acts in the spine as a crucial stabilizer, and as a mechanism for force distribution between the vertebral bodies. Without the disc, collapse of the intervertebral space occurs in conjunction with abnormal joint mechanics and premature development of arthritic changes.

[004] The normal intervertebral disc has an outer ligamentous ring called the annulus surrounding the nucleus pulposus. The annulus binds the adjacent vertebrae together and is constituted of collagen fibers that are attached to the vertebrae and cross each other so that half of the individual fibers will tighten as the vertebrae are rotated in either direction, thus resisting twisting or torsional motion. The nucleus pulposus is constituted of loose tissue, having about 85% water content, which moves about during bending from front to back and from side to side.

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[005] As people age, the annulus tends to thicken, desicate, and become more rigid. The nucleus pulposus, in turn, becomes more viscous and less fluid and sometimes even dehydrates and contracts. The annulus also becomes susceptible to fracturing or fissuring. These fractures tend to occur all around the circumference of the annulus and can extend from both the outside of the annulus inwards, and the interior outward. Occasionally, a fissure from the outside of the annulus meets a fissure from the inside and results in a complete rent or tear through the annulus fibrosis. In situations like these, the nucleus pulposus may extrude out through the annulus wall. The extruded material, in turn, can impinge on the spinal cord or on the spinal nerve rootlet as it exits through the intervertebral disc foramen, resulting in a condition termed ruptured disc or herniated disc

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[006] In the event of annulus rupture, the inner-nucleus component migrates along the path of least resistance forcing the fissure to open further, allowing migration of the nucleus pulposus through the wall of the disc, with resultant nerve compression and leakage of chemicals of inflammation into

the space around the adjacent nerve roots supplying the extremities, bladder, bowel and genitalia. The usual effect of nerve compression and inflammation is intolerable back or neck pain, radiating into the extremities, with accompanying numbness, weakness, and in late stages, paralysis and muscle atrophy, and/or bladder and bowel incontinence. Additionally, injury, disease or other degenerative disorders may cause one or more of the intervertebral discs to shrink, collapse, deteriorate or become displaced, herniated, or otherwise damaged.

[007] The surgical standard of care for treatment of herniated, displaced or ruptured intervertebral discs is fragment removal and nerve decompression without a requirement to reconstruct the annular wall. While results are currently acceptable, they are not optimal. Various authors report 3.1-21% recurrent disc herniation, representing a failure of the primary procedure and requiring re-operation for the same condition. An estimated 10% recurrence rate results in 39,000 re-operations in the United States each year.

[008] An additional method of relieving the symptoms is thermal annuloplasty, involving the heating of sub-annular zones in the non-herniated painful disc, seeking pain relief, but making no claim of reconstruction of the ruptured, discontinuous annulus wall.

[009] There is currently no known method of annulus reconstruction, either primarily or augmented with an annulus stent.

Brief Summary of the Invention

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[010] The present invention provides methods and related materials for reconstruction of the disk wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs.

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[011] In a preferred form, one or more mild biodegradable surgical sutures are placed at about equal distances along the sides of a pathologic aperture in the ruptured disc wall (annulus) or along the sides of a surgical incision in the weakened, thinned disc annulus.

[012] Sutures are then tied in such fashion as to draw together the sides of the aperture, effecting reapproximation or closure of the opening, to enhance natural healing and subsequent reconstruction by natural tissue (fibroblasts) crossing the now surgically narrowed gap in the disc annulus.

[013] A 25-30% reduction in the rate of recurrence of disc nucleus herniation through this aperture, has been achieved using this method.

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[014] In another embodiment, the method can be augmented by placement of a patch of human muscle fascia (the membrane covering the muscle) or any other autograft or allograft acting as a bridge in and across the aperture, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

[015] A 30-50% reduction in the rate of recurrence of disc herniation has been achieved using the aforementioned fascial augmentation with this embodiment.

[016] Having demonstrated that human muscle fascia is adaptable for annular reconstruction, other biocompatible membranes can be employed as a bridge, stent, patch or barrier to subsequent migration of the disc nucleus through the aperture. Such biocompatible materials may be, for example, a medical grade biocompatible fabric, biodegradable polymeric sheets, or form fitting or non-form fitting fillers for the cavity created by removal of a portion of the disc nucleus in the course of the disc fragment removal or discectomy. The prosthetic material can be placed in and around the intervertebral space, created by removal of the degenerated disc fragments.

Brief Description of the Drawings

[017] Figure 1 shows a perspective view of the annulus stent.

[018] Figure 2 shows a front view of the annulus stent.

[019] Figure 3 shows a side view of the annulus stent.

[020] Figure 4A-4C show a front view of various alternative embodiments of the annulus stent.

[021] Figure 5A-5B shows the alternative embodiment of a pyramid shaped annulus stent.

[022] Figure 6A-6B shows the alternative embodiment of a coned shaped annulus stent.

[023] Figure 7 shows the primary closure of the opening in the disc annulus, without an intervertebral or subannular stent.

[024] Figure 8A-8B shows the primary closure with a stent in generic form.

[025] Figure 9 shows a method of suturing the annulus stent into the disc annulus, utilizing sub-annular fixation points.

[026] Figure 10A-10B show the annulus stent with flexible bladder being expanded into the disc annulus.

[027] Figure 11A-11D show the annulus stent being inserted into the disc annulus.

[028] Figure 12A-12B show the annulus stent with the flexible bladder being expanded by injection.

Detailed Description of the Invention

[029] The present invention provides methods and related materials for reconstruction of the disk wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs.

[030] In one embodiment of the present invention, as shown in Figure 7, a damaged annulus **42** is repaired by use of surgical sutures **40**. One or more surgical sutures **40** are placed at about equal distances along the sides of a pathologic aperture **44** in the ruptured annulus **42**. Reapproximation or closure of the aperture **44** is accomplished by tying the sutures **40** in such a fashion that the sides of the aperture **44** are drawn together. The reapproximation or closure of the aperture **44** enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable, but permanent non-biodegradable may be utilized.

[031] Additionally, to repair a weakened or thinned disc annulus **42**, a surgical incision is made along the weakened or thinned region of the annulus **42** and one or more surgical sutures **40** are placed at about equal distances along the sides of the incision. Reapproximation or closure of the incision is accomplished by tying the sutures **40** in such a fashion that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable, but permanent non-biodegradable materials may be utilized.

[032] In an alternative embodiment, the method can be augmented by the placement of a patch of human muscle fascia or any other autograft, allograft or xenograft in and across the aperture **44**. The patch acts as a bridge in and across the aperture, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

[033] In a further embodiment, as shown in Figure 8, a biocompatible membrane can be employed as an annulus stent **10**, being placed in and across the aperture **44**. The annulus stent **10** acts as a bridge in and across the aperture **44**, providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture **44**.

[034] In a preferred embodiment, as shown in Figures 1-3, the annulus stent **10** comprises a centralized vertical extension **12**, with an upper

section **14** and a lower section **16**. The centralized vertical extension **12** can be trapezoid in shape through the width and may be from about 8mm -12mm in length.

[035] Additionally, the upper section **14** of the centralized vertical extension **12** may be any number of different shapes, as shown in Figures 4A and 4B, with the sides of the upper section **14** being curved or with the upper section **14** being circular in shape. Furthermore, the annulus stent **10** may contain a recess between the upper section **14** and the lower section **16**, enabling the annulus stent **10** to form a compatible fit with the edges of the aperture **44**.

[036] The upper section **14** of the centralized vertical extension **12** can comprise a slot **18**, where the slot **18** forms an orifice through the upper section **14**. The slot **18** is positioned within the upper section such that **14** it traverses the upper section's **14** longitudinal axis. The slot **18** is of such a size and shape that sutures, tension bands, staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent **10** to the disc annulus **44**.

[037] In an alternative embodiment, the upper section **14** of the centralized vertical extension **12** may be perforated. The perforated upper section **14** contains a plurality of holes which traverse the upper section's **14** longitudinal axis. The perforations are of such a size and shape that sutures, tension bands, staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent **10** to the disc annulus **44**.

[038] The lower section **16** can comprise a pair of lateral extensions, a left lateral extension **20** and a right lateral extension **22**. The lateral extensions **20** and **22** comprise an inside edge **24**, an outside edge **26**, an upper surface **28**, and a lower surface **30**. The lateral extensions **20** and **22** can have an essentially constant thickness throughout. The inside edge **24** is attached to the lower section **16** and is about the same length as the lower section **16**. The outside edge **26** can be about 8mm - 16mm in length. The inside edge **24** and the lower section **16** meet to form a horizontal plane, essentially perpendicular to the centralized vertical extension **12**. The upper surface **28** of the lateral extensions **20** and **22** can form an angle of about 0°-60° below the horizontal plane. The width of the annulus stent **10** may be from about 3mm-5mm.

[039] Additionally, the upper surface **28** of the lateral extensions **20** and **22** may be barbed for fixation to the inside surface of the disc annulus **40** and to resist expulsion through the aperture **44**.

[040] In an alternative embodiment, as shown in Figure 4B, the lateral extensions **20** and **22** have a greater thickness at the inside edge **24** than at the outside edge **26**.

[041] In a preferred embodiment, the annulus stent **10** is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well know in the art.

[042] For example, the annulus stent may be made from:
a porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus

fibrosus as disclosed in, for example, U.S. Patent Nos. 5,108,438 (Stone) and 5,258,043 (Stone);

a strong network of inert fibers intermingled with a bioresorbable (or biosabsorable) material which attracts tissue ingrowth as disclosed in, for example, U.S. Patent No. 4,904,260 (Ray et al.);

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a biodegradable substrate as disclosed in, for example, U.S. Patent No. 5,964,807 (Gan at al.); or

a expandable polytetrafluoroethylene (ePTFE), as used for conventional vascular grafts, such as those sold by W.L. Gore and Associates, Inc. under the trademarks GORE-TEX and PRECLUDE, or by Impra, Inc. under the trademark IMPRA.

[043] Furthermore, the annulus stent **10**, may contain hygroscopic material for a controlled limited expansion of the annulus stent **10** to fill the evacuated disc space cavity.

[044] Additionally, the annulus stent **10** may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica-based materials which assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

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[045] In further embodiments, as shown in Figures 5-6, the left and right lateral extensions **20** and **22** join to form a solid pyramid or cone. Additionally, the left and right lateral extensions **20** and **22** may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral

extensions **20** and **22** to be compressed for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall.

[046] Alternatively, a compressible core may be attached to the lower surface **30** of the lateral extensions **20** and **22**, forming a pyramid , cone, trapezoid, wedge, or bullet shape. The compressible core may be made from one of the biocompatible or bioresorbable resilient foams well known in the art. The compressible core allows the lateral extensions **20** and **22** to be compressed for insertion into aperture **44**, then to expand conforming to the shape of the annulus' **42** inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

[047] In a preferred method of use, as shown in Figures 10A-10D, the lateral extensions **20** and **22** are compressed together for insertion into the aperture **44** of the disc annulus **40**. The annulus stent **10** is then inserted into the aperture **44**, where the lateral extensions **20** and **22** expand, with the upper surface **28** contouring to the inside surface of the disc annulus **40**. The upper section **14** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **40**, using means well known in the art.

[048] In an alternative method, where the length of the aperture **44** is less than the length of the outside edge **26** of the annulus stent **10**, the annulus stent **10** must be inserted laterally into the aperture **44**. The lateral extensions **20** and **22** are compressed, and the annulus stent **10** is laterally inserted into the aperture **44**. The annulus stent **10** is then rotated inside the disc annulus **40**, such that the upper section **14** is pulled back through the aperture **44**. The lateral extensions **20** and **22** are then allowed to expand,

with the upper surface **28** contouring to the inside surface of the disc annulus **40**. The upper section **14** is positioned within the aperture **44** such that the annulus stent **10** may be secured to the disc annulus, using means well known in the art.

[049] In an alternative method of securing the annulus stent **10** in the aperture **44**, as shown in Figure 9, a first surgical screw **50** and second surgical screw **52**, with eye holes **53** located at the top of the screws **50** and **52**, are opposingly inserted into the adjacent vertebrae **54** and **56** below the annulus stent **10**. After insertion of the annulus stent **10** into the aperture **44**, a suture is passed down though the disc annulus **40**, adjacent to the aperture **44**, through the eye hole **53** on the first screw **50** then back up through the disc annulus **40** and through the orifice **18** on the annulus stent **10**. This is repeated for the second screw **52**, after which the suture is secured. One or more surgical sutures **40** are placed at about equal distances along the sides of the aperture **44** in the disc annulus **42**. Reapproximation or closure of the aperture **44** is accomplished by tying the sutures **40** in such a fashion that the sides of the aperture **44** are drawn together. The reapproximation or closure of the aperture **44** enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus **42**. Preferably, the surgical sutures **40** are biodegradable but permanent nonbiodegradable forms may be utilized. This method should decrease the strain on the disc annulus **40** adjacent to the aperture **44**, precluding the tearing of the sutures through the disc annulus **40**.

[050] It is anticipated that fibroblasts will engage the fibers of the polymer or fabric of the intervertebral disc stent, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

[051] In an additional embodiment, as shown in Figures 10A-B, a flexible bladder **60** is attached to the lower surface **30** of the annulus stent **10**. The flexible bladder **60** comprises an internal cavity **62** surrounded by a membrane **64**, where the membrane **64** is made from a thin flexible biocompatible material. The flexible bladder **60** is attached to the lower surface **28** of the annulus stent **10** in an unexpanded condition. The flexible bladder **60** is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity **62**. The exact size of the flexible bladder **60** can be varied for different individuals. The typical size of an adult nucleus is 2 cm in the semi-minor axis, 4 cm in the semi-major axis and 1.2 cm in thickness.

[052] In an alternative embodiment, the membrane **64** is made of a semi-permeable biocompatible material.

[053] In a preferred embodiment, a hydrogel is injected into the internal cavity of the flexible bladder **28**. A hydrogel is a substance formed when an organic polymer (natural or synthetic) is cross- linked via covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice structure which entraps water molecules to form a gel. The hydrogel may be used in either the hydrated or dehydrated form.

[054] In a method of use, where the annulus stent **10** has been inserted into the aperture, as has been previously described and shown in Figures 12 A-b, an injection instrument, as known in the art, such as a syringe, is used to inject the biocompatible fluid or expansive foam into the internal cavity **62** of the flexible bladder **60**. The biocompatible fluid or expansive foam is injected through the annulus stent **10** into the internal cavity of the flexible bladder **28**. Sufficient material is injected into the internal cavity **62** to expand the flexible bladder **60** to fill the void in the intervertebral disc cavity. The use of the flexible bladder **60** is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

[055] The surgical repair of an intervertebral disc may require the removal of the entire disc nucleus, being replaced with an implant, or the removal of a portion of the disc nucleus thereby leaving a void in the intervertebral disc cavity. The flexible bladder **60** allows for the removal of only the damaged section of the disc nucleus, with the expanded flexible bladder **60** filling the resultant void in the intervertebral disc cavity. A major advantage of the annulus stent **10** with the flexible bladder **60** is that the incision area in the annulus can be reduced in size as there is no need for the insertion of an implant into the intervertebral disc cavity.

[056] In an alternative method of use, a dehydrated hydrogel is injected into the internal cavity **28** of the flexible bladder **60**. Fluid, from the disc nucleus, passes through the semi-permeable membrane **64** hydrating the dehydrated hydrogel. As the hydrogel absorbs the fluid the flexible bladder expands **60**, filling the void in the intervertebral disc cavity.